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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,946	09/12/2003	Olga Bandman	PF-0114-2 DIV	7467

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EXAMINER	
HAYES, ROBERT CLINTON	
ART UNIT	**PAPER NUMBER**
1649	

DATE MAILED: 06/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/660,946	BANDMAN ET AL.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,9-12,17-27,44,45 and 48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,2,9-12,17-27,44,45 and 48* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2 & 17-18, drawn to purified NSPLP proteins, and pharmaceutical compositions thereof, classified in Class 514, subclass 12. Note that Applicants must elect either the polypeptide of SEQ ID NO: 1 or 3, in order to be fully compliant with this restriction requirement.

II. Claims 9-10 & 12, drawn to isolated and purified polynucleotides encoding NSPLP proteins, expression vectors, associated host cells, and method for producing NSPLP proteins, classified in Class 435, subclass 69.1. Note that Applicants must elect either the polynucleotide encoding the polypeptide of SEQ ID NO: 1 or 3, in order to be fully compliant with this restriction requirement.

III. Claims 11, drawn to antibodies that bind to NSPLP proteins, classified in Class 530, subclass 387.1.

IV. Claims 19, 22 & 25, drawn to a method of treating a disease associated with decreased or overexpression of a functional NSPLP comprising administering a NSPLP polypeptide/agonist/antagonist, classified in Class 514, subclass 2

V. Claims 20, 23, 26, 27 & 44, drawn to methods of screening for an agonist/ antagonist/antibody to a NSPLP polypeptide, classified in Class 435, subclass 7.21, etc.

VI. Claims 21, drawn to agonists that effect NSPLP activity, and pharmaceutical compositions thereof, Class/subclass varies.

VII. Claims 24, drawn to antagonists that effect NSPLP activity, and pharmaceutical compositions thereof, Class/subclass varies.

VIII. Claim 45, drawn to method of purifying a NSPLP polypeptide using an antibody, Class 530, subclass 413.

IX. Claim 48, drawn to microarrays that comprise oligonucleotides on a solid support, classified in Class 435, subclass 91.2.

2. The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relation of Inventions" in MPEP 806.05 for inventive groups that are directed to different products, restriction is deemed proper because these products appear to constitute patently distinct inventions for the following reason:

Groups I-III, VI, VII and IX are directed to products that are physically and functionally distinct involving proeins, nucleic acids, antibodies, agonists, antagonists and microarrays. Each of these products can be prepared by different processes, such as though chemical synthesis or isolation from natural sources using various isolation/ purification procedures. For example, the polypeptides of Group I, antibodies of Group III, agonists of Group VI and antagonists of Group VII are fundamentally different molecules than the nucleic acid molecules of Group II, which in turn can be used to clone the protein, detect expression of the protein, or used as therapeutic agents in gene therapy. The agonists of Group VI are fundamentally different molecules than the antagonists of Group VII, since the agonists of Group VI would activate the polypeptides of Group I, while the antagonists of Group VII would inhibit activity of the

polypeptides of Group I. The polypeptides of Group I are further distinct from the agonists of Group VI in that the only requirement for an agonist is the presence of a receptor binding domain, which can involve any type of chemical moiety or structure, while the polypeptide of Group I is made solely of amino acid residues. Similarly, although the antagonists of Group VII can be proteins or antibodies, any agent that blocks the activity of the proteins of Group I is an antagonist, including chemical compounds that have no structural relationship to the proteins of Group I or antibodies of Group III, and vice versa. The polypeptides of Group I can further be used in other ways, such as to generate the antibodies of Group III, functions not necessarily intrinsic to the agonists of Group VI or the antagonists of Group VII. Although the antibodies of Group III can be used in isolating the proteins of Group I, the antibodies of Group III can be generated by immunizing animals with a small synthetic portion of the full length protein, and can be used diagnostically in other ways, such as in affinity chromatography or in immuno-assays, or as therapeutic agents themselves. Nevertheless, the proteins of Group I can be utilized in making the antibodies of Group III, but not vice versa. The microarray of Group IX requires oligonucleotides, hybridization reagents and solid supports not required for the full length nucleic acids products of Group II. Lastly, neither the proteins of Group I nor the antibodies of Group III nor the microarrays of Group IX require the vectors and host cells of Group II, and vice versa. It is pointed out that there is a proper distinction between these groups, since each product is not required in order for the other to exist. Thereby, these groups are distinct and separable for the reasons stated.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the proteins of Group I can be used in materially different processes, such as in affinity chromatography to isolate NSPLP agonists, or to generate antibodies, etc. In contrast, although the method of Group IV requires the products of Group I, this method requires diseases and patients associated with altered expression of NSPLP to treat, as well as administration protocols, not required for the product of Group I.

Although there are no provisions under the section for "Relation of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed proper because these methods appear to constitute patently distinct inventions for the following reason:

Groups IV-V and VIII are directed to methods of treating patients (Group IV), screening for agonists or antagonists (Group V), or purifying a NSPLP polypeptide with an antibody (Group VIII). Each of the methods requires physically and functionally distinct elements. For example, the methods of Group IV require treating a patient with a protein (Group I) or agonist (Group VI) or antagonist (Group VII), unlike the methods of Groups V and VIII, and vice versa. Detection protocols are required in the method of Group V, unlike the method of Group IV, and vice versa. Likewise, test compounds are required in the methods of Groups V, unlike the methods of Groups IV or VIII, and vice versa. Agonists and antagonists are required in the methods of Group V, unlike the methods of Groups VIII, and vice versa. Lastly, each method is distinct because they require different starting materials, possess different method steps and assay conditions, and have different goals. These inventions are, therefore, patentably distinct, since one is not required for the other.

Because these inventions are distinct for the reasons given above, they have acquired a separate status in the art as shown by their different classification, and the non-coextensiveness of the search and examination for each group would constitute an undue burden on the examiner to search and consider all the separable groups with their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

4. Lastly, note that *In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) and *In re Brouwer*, 77 F.3d 422, 37 USPQ2d 1663 (Fed. Cir. 1996) addressed the issue of whether an otherwise conventional process could be patented if it were limited to making or using a nonobvious product.

> In situations where product and process claims drawn to independent and distinct inventions are presented in the same application, an applicant may be called upon under 35 U.S.C. §121 to elect claims to either the product or process. The claims to the non-elected invention will be withdrawn from further consideration. However, in the case of an elected product claim, when a product claim is found allowable, withdrawn process claims which depend from or otherwise include all the limitations of an allowable product claim will be rejoined. Withdrawn process claims not commensurate in scope with an allowable product claim will not be rejoined. In the event of rejoinder, the rejoined process claims will be fully examined for patentability. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert C. Hayes, Ph.D.
June 14, 2006

ROBERT C. HAYES, PH.D.
PRIMARY EXAMINER